PCAST Report Workgroup
Draft Transcript
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Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome to the second meeting of the PCAST Workgroup. This is a Federal Advisory Committee, so there will be opportunity at the end of the call for the public to make comments and there will also be a transcript of the call on the ONC Website. Just a quick apology, we don't have any Web access today, so I have sent you all of the slides. If for some reason you don't have them, send me a quick e-mail and I'll get it out to you, and also, a reminder to please identify yourselves when speaking.

Let me do a quick roll call. Paul Egerman?

Paul Egerman – Software Entrepreneur
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
William Stead? Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Hunt Blair?

Hunt Blair – OVHA – Deputy Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Tim Elwell?

Tim Elwell – Misys Open Source Solutions – Vice President
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Carl Gunter? John Halamka? Deven McGraw is here for Leslie Harris.

Deven McGraw – Center for Democracy & Technology – Director
Yes, my colleague, Harley Geiger, is on as well for Leslie. We're tag-teaming.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, Harley Geiger. Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Robert Kahn?

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Here.
Judy Sparrow – Office of the National Coordinator – Executive Director
Gary Marchionini?

Gary Marchionini – University of North Carolina – Dean & Professor
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Steve Ondra?

Stephen Ondra – NeHC – Senior Policy Advisor
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Here?

Judy Sparrow – Office of the National Coordinator – Executive Director
Richard Platt?

Richard Platt – Harvard Medical School – Professor & Chair
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Mark Rothstein?

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Steve Stack?

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Eileen Twiggs? \William Press, the first speakers on the telephone. Did I leave anybody off?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Bill Stead's here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Oh, good, thank you. With that, I'll turn it over to Paul Egerman.

Paul Egerman – Software Entrepreneur

Thank you very much. I want to welcome you to our second conference call of the PCAST Report Workgroup. As Judy said, we are an advisory workgroup that will report to both the HIT Standards Committee and Policy Committee, although primarily to the HIT Policy Committee. As I said, this is our second meeting. The first meeting was spent really discussing and describing our charge, and I'm going to review that in a minute. I also want to briefly address members of the public who might be listening to our call. I want to thank you for your participation.

I do want to apologize to you that we do not have Web access available to you, which might make it difficult to follow through on some of the PowerPoint presentations. If there are any members of the workgroups, the Policy Committee or Standard Committee workgroups, if you are attending this call, if you send Judy Sparrow an e-mail, I'm sure she will send you a copy of the PowerPoint presentation to make it possible for you to follow along. If you're a member the public and you have Judy's e-mail, I'm sure she can send it to you also. We would like you to participate and, as Judy said, there will be an opportunity for public comment at the end and we place a huge amount of value in those public comments.

The main goal of our call today is to try to gain some additional understanding of the PCAST Report. If you have the slides in front of you—not the Bill Press slides but the ONC slides—I do want to point out slide number four to you, where it says, "Our Workgroup Charge." This is the workgroup charge that we discussed last week, where it says where to basically synthesize and analyze the public comments. We're going to discuss the implications of the report on current ONC strategies, assess the feasibility impact of the report on ONC programs, and elaborate on how these recommendations could be integrated into the ONC strategic framework. You'll notice that there's one section, however, in red, where it says, "Discuss the implications of the report and its specific recommendations to ONC." That was added after the discussion last week, and the reason we added that is we wanted to make it clear that this workgroup is really focused on the aspects of the PCAST Report that relate to ONC. There are some sections of the report, for example, that deal with CMS. Those are very interesting, but that's not where we are going to roll up our sleeves. We're only going to deal with the ONC part, which is really the information exchange and DEAS and security and a lot of very interesting and exciting issues.

If you look at slide number five that has the meeting dates, I want to make sure we spend most of our time listening to Bill Press, so I'm going to return to this after he finishes speaking. I just want to make sure that I point out that the next meeting after this one is on January ..., and Judy Sparrow, is it correct that we've confirmed February 15th and 16th, or is that not confirmed yet?

Judy Sparrow – Office of the National Coordinator – Executive Director
No, that is confirmed. I'll be sending out a calendar once I find out where we will be meeting.

Paul Egerman – Software Entrepreneur
Okay, so again, I'm going to do this again at the end of the call, but I do want to confirm, on the slides it says "15th, 16th or 17th" as one of these dates, it's actually going to be February 15th and 16th for a hearing in Washington, D.C. So I'd ask everybody if they can do their best to hold both of those dates. It's going to be a day and a half meeting; all day on February 15th and half a day on the 16th. For those of you who are members of the HIT Standards Committee, the Standards Committee will be meeting on the afternoon of the 16th, so you don't have to go back and forth twice. For those of you who are members of the Policy Committee who may be listening on the public line or on this call, you are welcome to attend. All Policy Committee and Standards Committee members are also invited to attend the workgroup hearings and participate in the hearings with us.

Again, I'm going to talk a little bit more about the meeting dates but I do want to make sure that we get as much time as we can for Bill Press. Before I introduce him, do you have any comments, Bill Stead?

William Stead – Vanderbilt – Chief Strategy and Information Officer
No.

Paul Egerman – Software Entrepreneur

So, Bill Press is the Vice Chair of PCAST, which is probably the job that does the most amount of work. He certainly has been very deeply involved in this project and he's put together a presentation, so I thank you in advance, Bill, for spending time with us. Before you do get started, one quick comment. Looking at your slides, you say in advance in your slides that people need to have technical skills. If there are workgroup members who feel a little bit lost in his presentation, I do want to assure you that our work is really not primarily technical. We'll be working at a higher level. If you have any questions or issues, be sure you let me, or Bill Stead, know and we'll do our best to respond. I'm looking forward to this, so, Bill Press.

Bill Press – PCAST – Vice Chair
By way of introduction of myself in about 20 seconds, a little bit beyond Paul, I should say, my training is as a physicist and I was a Professor of Physics at Harvard for more than 20 years. More recently, in the last few years, I've been working in computational biology and I'm in both the Biology Department and the Computer Science Department here at the University of Texas at Austin. That's actually by way of apology. If I'm overly technical, you can blame it on my physicist background.

I'm going to go through my slides, and to keep you people synchronized I'll try to be sure to say what slide number I'm on. When I change slides, I'll try to pause in case anybody wants to interject a quick question or comment. Then, Paul, if I understand correctly that most of the discussion will be after I go through the slides, is that the way you do it?

Paul Egerman – Software Entrepreneur
You can go through it all or you can do interruptions, whatever you prefer. The way you asked that question, I sense that you prefer afterwards.

Bill Press – PCAST – Vice Chair
I think afterwards is probably better, unless there's something that I'm just explaining badly that someone would like to interrupt on, and in that case please feel free.

Paul Egerman – Software Entrepreneur
Okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul, would you mind reminding people to mute their phones? There's someone typing into the phone.

Paul Egerman – Software Entrepreneur
Thank you. I think you just did that, Dixie, but yes, please mute your telephones right now if you are not Bill Press.

Bill Press – PCAST – Vice Chair
I'm now on slide two, which is just what the scope of this briefing is supposed to be. I am going to assume that you've seen the report. I give, on slide two, what the reference is to the report. It's easy to find by Googling it. I'm assuming that here we're interested in seizability and implementation issues. A lot of the report is about why more and better health IT is needed, what are the use cases. I'm going to quickly go over a briefing that summarizes that part of the report, but the best briefer on that is probably the co-chair of the report, Chris Cassel, who ... a physician.

Can I just ask, are other people hearing that too loud—?

Paul Egerman – Software Entrepreneur
Those are people trying to use the phone system to mute their line because their phone doesn't have a mute. I don't think we can do anything but tolerate it, I'm afraid.

Bill Press – PCAST – Vice Chair
Oh, okay. At least we know what it is. As Pau said, I've prepared this briefing on the assumption that I should concentrate on somewhat a technical level, if only because those are the parts of the PCAST

Report that are perhaps not explained in the same level of detail as are the policy parts and ... parts. But I don't want it to be so technical that people aren't interested in the discussion, so one of the co-chairs please tell me if you want me to come up a level or two.

Importantly, I'm including in this briefing both things that I think are simply objective summaries of what's actually in the report, and on my slides, I have a little picture of the report cover denoting that kind of content. But I also think it's important to go beyond that and give you my individual interpretations and comments and on the slides they're denoted by that little cartoon of a professor in a white coat. I don't look like that, I hope. The real purpose of that little icon is, those are parts that if you have a better idea, then do the better idea. In other words, I think the PCAST Report Committee definitely had the sense to try to establish general directions and general goals and not over specify what the solution ought to be. So with those caveats, I'm now turning to slide three.

I'm getting a little bit of echo. I don't know if anybody can do anything about that, probably not.

On slide three, the overall report tries to find a path that meets the needs of multiple constituencies. We would see those constituencies, as I think most people would, as divided into three categories. First of all, patients: It's pretty clear, we think, that the overall direction of healthcare delivery is moving towards being patient-centric as distinct from institution-centric care, and that health IT is either a or the technical vehicle for allowing this to happen. An implication is that in the future patients will be more and more involved in their own care. Another implication is that we need to take greater care in how we import privacy protection to the data associated with each patient.

The second big constituency is of course providers. Health IT can play the role of providing better data to providers in every medical encounter for better decisions. In the ideal case every provider should have access to the relevant parts of what they need from complete patient data, plus the data should be available for use in clinical decision support systems as they're developed. Quality measures are another kind of data that we want on the provider side. The goal from a provider point of view is to create efficiencies that lead to lower costs and better work conditions for people in the industry.

The third constituency, the public, also has a couple of different interests. The first interest of the public is in population data for public health and for comparative effectiveness research. That's been much discussed and is discussed in some detail in the report. The second point on my slide here about the public I put in blue, because I think this is where the PCAST Report is particularly interested in opening up the discussion beyond simply an existing provider or patient network framework. The point is that the public has an interest in opening Health Information Technology to the creation of new knowledge industries, to create an environment in which new entrepreneurial ideas can flourish.

Skipping down to the third sub-bullet here, just last week in San Francisco there was a JP Morgan event that was hosted by John …, and I guess others, that highlighted growing investor interest. I wasn't there but I'm told that John … in his introduction said that he believed that there are at least several new billion dollar a year class companies waiting to be formed around new entrepreneurial ideas relating to Health Information Technology. These kinds of new industries will create new and better jobs and in particular we can develop things in the U.S. that are of interest globally and that fuel the international export market. So PCAST, constituted to advise the president, felt that I guess that the jobs side of this, the new and better job side of this was not a negligible part of the direction in which we should be going in Health Information Technology.

I'm going to move to slide four now and stop for just a second for any interjections.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
On that first slide, ... any system that you build is going to have to deal with what I don't consider directly healthcare provider, but they're part of the provider system, maybe that's what you meant. For example, the labs that take specimens and process them, the pharmacies that fill the prescriptions and the like. Normally when they say "providers," they mean healthcare providers, thinking of the doctors and the

hospitals as opposed to the rest of the ecosystem there. Why wouldn't you actually call out the rest of the ecosystem specifically?

Bill Press – PCAST – Vice Chair
I accept your point completely. That's just my shorthand in making this slide. I think the report is clearer on that point. That's a welcome, friendly amendment to that bullet.

Stephen Ondra – NeHC – Senior Policy Advisor
Just one possible fourth bullet would be information for policy makers, be that ... or private because that information can help guide policy decisions that will impact the incentives to use the data to accomplish the above.

Bill Press – PCAST – Vice Chair
Yes, I agree with that. I guess my point on this slide is I couldn't really put the whole report in this slide and this slide and then the next one I'm sort of rushing through the overview to get down to what I think is also more my expertise, the implementation side of this. So again, I'm happy to accept that amendment.

On slide four, the PCAST Working Group and PCAST as a whole looks hard at this question: what are the barriers to all these good things, abbreviation for all of the previous just happening and are there barriers? Is the current state of progress compatible with reaching, for example, the goals that the president has articulated? PCAST strongly believes that there are barriers and that additional effort is needed to surmount those barriers. Here again I'm trying to summarize many pages, probably tens of pages in the report, in just a small number of bullets with all of the same dangers as the last slide. But some of these barriers are what here I've called, and I think the report doesn't use this word, but a set of "perverse" incentive structures. In fact, as everyone understands it, fee for service rewards volume, it doesn't directly either quality of care or efficiency of care directly. There's little or no return on investments by providers, and now I guess I mean mainly providers in the narrower sense, for investing in efficiencies, except efficiencies in billing and efficiencies in administrative work. In the current incentive structure, this is pre-meaningful use, few, if any, incentives for data sharing across provider system boundaries.

Not surprisingly, the installed base of legacy health IT systems mirrors the incentive structure that we presented. The installed base—and here I know we can get into arguments so I'm giving what is perhaps a cartoon description of the installed base, but I think it's fair to say the installed base tends to be vertically integrated, proprietary systems that were acquired in most cases as business decisions coming from the business side of the practice. Whatever practice means here, because it could be anything from a small practice to a huge health system. I don't think there's much debate that in the vertical stack by the time you get down to the user interface that the clinician sees those are user interfaces that are generally rated poor by the users, and these systems have historically had few data sharing capabilities.

Another characteristic of the installed base is a focus on, again, slightly a cartoon representation, the standardized patient record; whereas, the PCAST Report is trying to shift the focus of this away from the record and in the spirit of patient-centric to the idea that there's a patient and there's data and the data here is a plural now. Data is made of many datums and the focus on the patient's data is a somewhat different focus from a focus on standardized record, or at least a different viewpoint from which to proceed. And especially people like me that are new to health IT but not new to IT generally, there's been, within health IT, remarkably little adoption of what by now we would consider well-established Internet technologies. That's of course a judgment call, but as PCAST assembled its working group and we went around the table there was very little disagreement on that. It was remarkable, and not in a good way. Of course, we're all here because there is the possibility of these things, because meaningful use offers the opportunity to recast these incentives that have perhaps pushed us into an odd corner. So the goal is of course to use meaningful use to lower these barriers to technological progress. So I'm now about to turn to slide five, but we'll again pause for any quick interjections.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Do you have a sense that meaningful use is a substantial incentive when compared to the incentive structures that we've had? I mean, a few million dollars to a hospital compared to the punitive change in their annual billing because they're doing fewer lab and radiology exams, doesn't seem like it's a really substantial economic lever.

Bill Press – PCAST – Vice Chair
I think there are other people on the call who are much more expert in this than I am. I think on the PCAST side, it would be Chris Cassel who could give you a sophisticated discussion of this, but here's my sense. My sense is that although the dollar values of the meaningful use incentives do seem small, the industry is more likely to follow the path of meaningful use than you might expect. In part because they see the handwriting on the wall, the directions that are now incentivized by meaningful use by what amounts to cash could in the future become enforced directions in other ways. Why be forced later if you can get paid even a little bit for it now? Now, I understand that's not a very nuanced discussion, and as I say, it's a big policy question, but generally—and I guess the second answer as viewed from the PCAST committee was this is what we've got to work with right now. One should move out with the tools one has, bookmarking the whole separate policy discussion of what would be the longer term. Does that—?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. I'll let you off the hook.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I wanted to better understand one of the comments that you made, because I'm not sure I did. I'm going to just put the pieces together and maybe you can put them together in your view and tease them apart for me. You said at one point that the report said that there was some kind of agreement on use of established Internet technology and I keep thinking about, well, what about how you deal with new technology in the future, that there was widespread agreement in PCAST about either that or something related to it, but that was not necessarily good. Could you elaborate on that just a little bit for me?

Bill Press – PCAST – Vice Chair
Yes, a lot of this will be later in my talk. I should ask Paul how worried I should be about using up time here.

Paul Egerman – Software Entrepreneur
I tell you, Bill, it's up to you. I do want to make sure you get through your entire talk, though. You should do whatever is comfortable.

Bill Press – PCAST – Vice Chair
Okay. Bob, I guess what I'd do then is ask you to defer the question to see if it gets answered later on.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
So there's not a 30-second answer right now? If it's a longer one, that's fine. If it's real short then I'm happy to take it now.

Bill Press – PCAST – Vice Chair
Let's wait on it.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Okay, fine.

Bill Press – PCAST – Vice Chair
I'm now on slide five and we're getting down into not just what is the problem and what are the possible opportunities to change it, but what PCAST really sees as the critical leverage points to move forward on this. I think we've come down that there are two parts, they're interconnected, you can't really have one be very useful without the other, but they're distinct. The first is a universal exchange language. Now, this picks up from my point that we want to start looking at the patient's data rather than the standardized record. This goes immediately to the idea that the data should be disaggregatable and re-aggregatable

so that the data can be used for many purposes. If you want to be very specific, it can be displayed by many different software apps in different clinical situations, appropriately anonymized, used in public health situations, and be able to move data about either individual patients or a population of patients not by moving full records but by moving the relevant pieces of data. The way to do this is the … plus metadata tags.

This gets us to, there was some discussion before the call started on is XML the magic bullet, what do we mean by XML? In this case, we use the term XML at a higher level to be pretty much interchangeable with the idea of a versatile data format that can encapsulate data itself and metadata that travels with the data in various hierarchical ways, which, however, software is able to take apart the hierarchy and reuse. I guess I ought to be a better professor of computer science than that explanation indicates, but when we say XML-like, I think we really just mean the basic underlying idea within XML that says you can package data with metadata attached. You can make packages of packages and so on in a universal way, in a way that many different kinds of software can understand.

It's important we think that the universal exchange language be highly extensible, highly evolvable, and that it be open in the usual sense of open software but in some other senses that I'm going to define in just a minute. We think that in exchange language like this, especially with the ability to package data with metadata can support and along with appropriate regulation in force, fine-grained models of privacy in a way that patient records now don't have, whether it's electronic or paper records, for that matter. We think that a universal exchange language can be designed in such a way that there's an evolutionary path for current systems without losing the investment in current systems or having to instantly reengineer them. That path is basically middleware, namely, since this is an exchange language you can put a piece of software in between your current system and the network, if you will, the medium of exchange, to do the translation into and out of this universal exchange language. The key point being that if you have a large number of different systems that don't talk to each other you don't want us to have to write software for each one to translate to each other one. That's an N squared problem, we would say. What you'd like to be able to do is simply have middleware that can go from each one into the universal exchange language and then all other ones can read it.

The second major bullet on this slide which is the second critical leverage point that we see is sunset of data element access services. That's just a term that we coined to be able to have a noun to talk about this stuff, so we call them DEAS, or DS. An example of a data element access service would be a service that finds a patient's records without the need for a uniform patient identifier. It sounds like magic, but I'm going to talk about that on later slides. We believe that's quite feasible. This is part of the 30-second answer to Bob Kahn's question, with "Web search technology." Another example of data element access service would be the enforcement and management of privacy, in particular to manage a cryptographic infrastructure that deals with all the transactions in which data moves around and to be maintain an audit trail on all those transactions, and I'll come back to these points in a later slide.

I'm now moving to slide six, so—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
May I ask a question, Bill? Regarding the fine-grained privacy, when your group discussed this were they still—

Paul Egerman – Software Entrepreneur
Dixie, let's hold off on that. I think he's going to talk about that in a minute, so hold off on it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, I'll be happy to. Thank you.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Are you going to talk also about the universal language or is this a good place to ask a question?

Bill Press – PCAST – Vice Chair

Yes, I am. In fact, I think the very next slide is more on the universal language a bit, so you can save that. I think I have to be respectful of everybody else's time. I'm happy to go on at any length in the discussion period, but I think Paul's right, that I should try to push through these slides as fast as I can and then we'll come back.

On slide six, this is discussing the universal exchange language and it's making the important distinction between syntax and semantics. Because we think that getting this distinction right is a way of accelerating progress towards this universal exchange language, so what do these mean? Syntax, it means how do I format a message, for example, using an XML-like language, I should say, how do I format a message independent of what it means so that it can be transmitted, encrypted, decrypted, and processed by a wide range of software applications or infrastructure. Syntax gets the data there but doesn't tell the program what that data means with respect to the actual state of health or identity of the patient. The meaning of those things is of course what we would call semantics.

The magic of—if I can call it that—XML or XML-like languages, in our view is it allows you to make a clear distinction along these lines. Namely, you can clearly define a lot of necessary syntax, essentially everything you would need in an exchange language, and do this independently of what are the semantics that go along with it. So the PCAST report basically says a good path forward is establish syntax and along with that some minimal set of required metadata that has to be included, so that's a little bit semantic, but the minimal set is essentially to be sure that privacy and security stuff and patient identity stuff is engineered in from the very beginning. Then on the semantic side, leverage a lot of existing work to essentially plug in existing semantics as vocabularies, taxonomies, and so on, into this syntax that we can get going rapidly on.

Here I think is the key point that the report makes about this. Don't wait for perfect harmonization on the semantics. In other words, if we hold up getting the packets actually moving and actually being exchanged until we have perfect harmonization or even near perfect harmonization on the semantics, we'll wait forever. Instead, we think that one could provide a structure in which there are multiple semantics at the same time and market forces essentially bring them together. So, for example, there are existing vendors who presumably have internal semantics in their proprietary systems. There would be a first to market advantage to those vendors if they essentially do a bit of repackaging of their semantics and say here's the semantics that we'll plug right in to the universal exchange language syntax. So suddenly, we're leveraging private effort, or I should say also not-for-profit NGO professional association kinds of efforts, into the semantics question.

We think that there can be and will be market incentives that will drive harmonization probably more efficiently than a purely government process could be. If I want to found a company and sell you middleware, it's going to be a key selling point that my middleware speaks more vocabularies, in other words, can access more of the standard published semantic realms than your vocabulary can. We also think that it's important that the semantics space, the space of meanings, not be closed, that there not be a government eye of the needle through which semantics have to pass. Because we anticipate that there could be new diagnostic equipment, there could be new meta-analyses of records which would have their own specialized semantics and with as little interference as possible essentially perhaps certify only for interoperability. You want new vendors to be able to publish in some recognized way their own plug-ins into this universal exchange language, and then someone might say well, that's just chaos. Everyone will publish their own specialized semantics and no one will know what they really mean. Well, that's not a very good business model for them. That's not going to sell their new piece of diagnostic equipment if existing software and middleware doesn't recognize it.

So that's part of their problem, not part of our problem. I'm saying that in an easy way, but that's kind of the overall orientation. In this semantics side of things, the PCAST folks really believe that the better is the enemy of the good and that there's a lot of good work out there that could be quite readily plugged into a universal syntax based around XML. Okay, this is the first slide where I've got somewhat technical so I'll again stop for any interjections before I go on to slide seven.

Robert Kahn – Corporation for National Research Initiatives – President & CEO

Since I'm one of the folks that would clearly be in the technical camp here, I'm having trouble understanding whether I agree completely with what you're saying or disagree completely, because I can't really tell. Let me tell you what I mean by that. When you talk about multiple semantics, I can imagine, because we've been thinking about these things a long time, an approach that would have one way of dealing with semantics that involves a resolution step so that you can have what you call multiple semantics, which all become part of the universe of semantics. Then the question is do the end systems have an ability to understand this semantics or the other semantics, but the basic operation of the system is almost insensitive to that. That is, when you've got things in there the semantics are my identifier, which then resolve to what the semantics mean and either you can understand them or you don't. So you can have a million different semantic packages and it's all the same system that can be used to resolve them.

Bill Press – PCAST – Vice Chair
Yes, I agree with that description. I think that's a good description. Does that mean you did agree with it or didn't agree with it?

Robert Kahn – Corporation for National Research Initiatives – President & CEO
If that's what you agree with, then I agree with you completely. But if it's meant that you have this semantics in the system and that's what you have to use, or this one in the system and it's all built into the guts of the language—

Bill Press – PCAST – Vice Chair
No, no, no, absolutely not. It's the first way you described it. That's absolutely what we mean.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Okay, then I'm in serious agreement. Thank you.

Paul Egerman – Software Entrepreneur
Bill, on this topic, I'm not sure I'm understanding it correctly. Is this also an issue in terms of coding? Is it one group can use SNOMED code, somebody else can use ICD-9 and you're sort of saying people can do what they want. Am I interpreting this right? Or is that—?

Bill Press – PCAST – Vice Chair
Yes. What we're saying is people can do what they want, but we believe that what they want is going to be rational and what they want is not going to be to use one kind of coding if the entire world is using the other. Now, what if there are two approximately equal camps? Well, it's no worse than the current situation where they can't talk to each other at all. It's much better because it creates the immediate opportunity for someone to make a piece of middleware, to make a product that plugs into this which does exactly what Bob Kahn said, that masks these two codings, either one into the other or both into a common semantic.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is Wes Rishel.

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Let me just say how this would work in practice. The universal language would all be identifier based, and so what shows up at a given site is either going to be understandable or not based on resolution of those identifiers into the local semantics that apply. So the universal language is standard and sort of semantics independent, it's just the identifiers that convey the semantics.

Paul Egerman – Software Entrepreneur
Wes Rishel, go ahead, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, I think every industry thinks they're different and healthcare really is. If that's a true statement, it's because we have gone so much farther down the road of standardized ontologies over the last 50 years

than other industries have, and particularly right now it's a physical impossibility to write mappings between ICD-9 and ICD-10 diagnosis codes, which are the required current generation and required next generation in the United States. So I'm wondering to what extent this thought that different ontologies could create some mapping opportunity is a bit of magical thinking.

Bill Press – PCAST – Vice Chair
Okay, let me try and answer that. If a mapping is possible, then it creates the opportunity that's sort of circular. What if, as you say, it's not possible, then what happens today? What happens today is there's a user, or I guess I should say an app, which might be actually a person's brain or it might be a piece of software, which has to decide what to do on the basis of either a code that's coming out of version 9 or a code that's coming out of version 10. So even if it can't map them into each other, it clearly has to be able to perform its function on either set and that would remain true here. So as Bob says, there would be an identifier that comes in that says I'm going to describe the diagnosis code to you and I'm using version 9. Now, either you understand that or you don't. If you understand version 9 but not version 10, then that's exactly the problem we'd be in today if you had software that was not upgraded to version 10. I don't know, did that add anything to it?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That depends on whether there's an implication here that the availability of universal access and mapping eliminates the requirement to set standards such as using version 9 or version 10.

Bill Press – PCAST – Vice Chair
I think it's silent on that issue. I think that's a policy issue, but I think what we're providing is a way that you can use these existing ontologies according to whatever policy you decide and they all will plug into the language.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Understood, thanks.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I'm pretty technical in this area as well, it seems to me there's another part. Maybe you're including that in either the syntax or the semantics, but if for instance we said we're using XML and even if we assumed we're using that, a tagged name value pair or an entity attribute value sort of strategy, there are all kinds of opportunities to represent the data differently. So just a fairly simple example would be that you can have a single code that means oral temperature or you can have one code that said here's a temperature with its value and then temperature location or temperature method and that would have a value of oral. So that you're doing things as a single name value pair where you've pre-coordinated more information into a single code or broken it out in more fine-grained information. That problem isn't solved by simply saying we're going to use a name value tag strategy plus this terminology, or this set of terminologies even. Did you explore that space of difference in this discussion?

Bill Press – PCAST – Vice Chair
Again, I'm mindful of the time. I think the short answer is did we discuss this kind of thing? The answer is yes, definitely. The short answer here is I think if you took that example you could tease out the pieces of it that are syntax from the pieces of it that are semantic. It might be that both ways of reporting oral temperature are allowed, but the metadata that goes with it says which method it is. So if it's one method there's an identifier, there's a tag that says I am a piece of data reporting oral temperature and I am using convention 2011.something.something.something to do so and then there's encapsulated one or more pieces of the data or metadata that perform that.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And that's I think the approach that we've taken already in many of these instances. But I guess the thing that maybe wasn't explicitly stated is that that kind of ability to inter-convert depends on having a shared library that has that 100.2.whatever as an identifier of a particular style of model that allows that.

Bill Press – PCAST – Vice Chair

Yes, that's great. But I think what we're saying is don't think of that conversion as a property of the exchange language. Here we're talking about the exchange language and when I want the exchange language to be neutral on those issues then we want the plug-in semantics to be where you take a policy position on what and how the meaning of what you want to report is.

Okay, I'm going to just press on, because—

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One other short question, because I don't see any other discussion of DEAS. The DEAS part seems to be very similar to some of the smart platform activity.

Bill Press – PCAST – Vice Chair
Well, wait, I want to interrupt to say that all of my remaining slides are about DEAS. They just don't have the term there, so let me—

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Okay, but I wondered in particular, well, it looked like the rest of the slides were about the sub-structure related to the metadata and—

Bill Press – PCAST – Vice Chair
No. I'm going to press on, sorry. Then let's come back to this if we have time.

Paul Egerman – Software Entrepreneur
Bill, I encourage you to rush through the slides and then we'll answer questions.

Bill Press – PCAST – Vice Chair
I'm now on slide seven. I have only ten slides but the last one is a whopper so we'll see how that—

Paul Egerman – Software Entrepreneur
I can hardly wait for that one.

Bill Press – PCAST – Vice Chair
On slide seven, we're talking about a particularly important kind of metadata because it has to be engineered in from the start, and this is the metadata related to privacy protection. What the report says is that all data elements as part of the language standard, so really as part of the syntax standard, all data elements carry and are bound to, in the usual cryptographic ways, privacy metadata. That obedience to whatever privacy policies are is enforced by engineered features in any software that speaks this language or that is certified by ONC, but also must be enforced by appropriate legal and regulatory measures that you need this across the board because you can't rely on engineered features alone. You can't rely on regulatory measures if there are not engineered features.

Now, in terms of how this relates to the discussions of the language, it's similar to the other semantics discussion, namely, you could spend forever trying to get an incredibly nuanced privacy vocabulary that could adopt to any envisioned future policy or set of policies and describe it without change. We think that's just not necessary to proceed. We think that you can get started with a simple privacy vocabulary because frankly the current granularity of privacy isn't very .... Because of the way metadata works in this language, because of the language structure, as policies change you can essentially bring out new versions of the privacy vocabulary in such a way that systems will honor the most up to date version that accompanies the data. I don't want to get into too much detail here, essentially the standard way one builds systems in advance so that they'll be able to speak later and later versions on some subsystem.

Okay, I'm going to press forward to slide eight now.

Gary Marchionini – University of North Carolina – Dean & Professor

So did PCAST discuss at all the efficacy of people actually adding this privacy data to their records? Given the lack of anybody adding metadata to their Word documents, to managing their passwords in a sensible way on various systems we use. What's the practicality here? Was that discussed at all?

Bill Press – PCAST – Vice Chair
Yes, sure. I think the vision you should have here is not that a human in any way laboriously adds to privacy metadata, it's that systems that speak this language add the privacy metadata when they generate any piece of data and they check the privacy metadata when they use any piece of data.

Gary Marchionini – University of North Carolina – Dean & Professor
Right, so I can see that working with healthcare providers possibly, because they could have the club of governance. But individual people, it seems to me like the default could pretty easily be yes, just anybody can use anything—

Bill Press – PCAST – Vice Chair
Well, okay.

Gary Marchionini – University of North Carolina – Dean & Professor
—... down to each individual data item.

Bill Press – PCAST – Vice Chair
So, again we're not trying to say what the privacy policy should be here, we're just trying to say what are the language features you need so that the language can enforce whatever the privacy policy is. Now, if you had a privacy policy that said know this field must be filled on each data or the data will not transit the system, you can certainly do that.

Gary Marchionini – University of North Carolina – Dean & Professor
Okay. I just wanted to raise that point.

Bill Press – PCAST – Vice Chair
Yes. Okay, good.

Paul Egerman – Software Entrepreneur
Bill, I ... the Webcast and I thought I heard Christine Cassel say patients could change the privacy of individual data elements themselves then with better privacy as a result. I thought I heard that patients would be able to manipulate at an atomic level privacy data. Did I misunderstand that?

Bill Press – PCAST – Vice Chair
Yes and no. This is a set of issues on which I guess Leslie Harris—no, not Leslie. Who's on the call from—?

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw.

Bill Press – PCAST – Vice Chair
Yes, Deven is on the call. Deven and Leslie sensitized us to this set of issues actually rather late in the game of preparing the report, and we thank you for that. The language should provide the ability to do that kind of fine-grained policy manipulation by the patient. That is not to say that PCAST is advocating for a policy in which that may necessarily happen. But the policy may not allow the patients to do that at all, it may allow the patients to elect only from some large categories of kinds of privacy protection for kinds of data. The policy issues the PCAST Report is essentially silent on, but the enabling a wide range of policies all the way down to the kind of atomic control that you describe is—I've gotten lost in my sentence here. The PCAST Report does want the exchange language to be able to transmit that kind of fine-grained information. Does that help?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Your original statement seemed to carry an implication of forward compatibility of privacy bindings. That is to say that data that was prepared at a certain point in time with certain statements in your language could be interpreted under future policy requirements because of this forward compatibility. If that is in fact an assumption, I think we have to recognize that most policy is created by state legislatures with little attention to the issue of forward compatibility of requirements.

Bill Press – PCAST – Vice Chair
Yes, I think that's a very good point. That's actually, what I was trying to get at in a very elliptical way on the very last line of slide seven. In other words, you could have a set of policies that allow you to interpret earlier versions or you could have a set of policies in which if the privacy metadata on a piece of data is simply noncompliant with a legislative requirement, a regulatory requirement. The system generates a request back to the data holder and says I cannot legally use your data or transmit your data until you update the privacy information on it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So then the question is, is it the data holder, often the care delivery organization that's the steward of the data, that is able to say for the patient what their requirements are? Or, does this generate a bunch of e-mails to patients who don't know what it's about and are confused by it?

Bill Press – PCAST – Vice Chair
Well, that's a policy question. The language should be able to do any or all of those things so as to implement whatever sane and sensible policy turns out to be. So I appreciate that these policy issues are very important, but the PCAST Report in many cases specifically tried not to take positions on what the policy should be, but only on what the health IT should be to enable a broad range of policies.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
We'll have a policy discussion later, but I would just like to flag the comment that this system, this structure is a technical option holder, where we could attach to it any sort of policy that we want even down to the most granular level. I think an argument could be made that that's the reverse of what we ought to be doing. That we ought to be starting with the policy and then figuring out the best way to implement that policy even though we want to have maximum flexibility, because there are downsides, which we won't go into now, about this sort of structure.

Paul Egerman – Software Entrepreneur
Excellent comment, Mark. I have similar concerns, so that's a good issue for us to put out on our parking lot or on our list, whatever the right expression is, that we need to address. This also ... the case that privacy policy data element oriented ... issues here.

Bill Press – PCAST – Vice Chair
I think those are great comments and I'm going to press on to slide eight. Slide eight is about patient identity and record location, and this is one of the key DEAS services. The PCAST Report says a uniform patient identifier is not required, essentially that's a decision to not wade into the deep end murky politics of what if you tried to say that a UPI was required. However, it's not just an assertion. We really looked into, at some level, what kinds of identity resolution technology exists in other industries and is it good enough to get started, and we strongly believe that it is. We also took as essentially a starting condition that there not need to be one DEAS, one master presumably federal database, but that there could be multiple federated databases. They would be intercommunicating in real time, but they could be either individual state-based, they could conceivably and in some cases grow out of existing large provider networks.

The key thing is that they be built to common standards and be in real time inter-communicating. The basic idea here is really nothing magical, it's how do we locate patient information now, absent uniform patient identifiers, and we ask you what's your last name, your first name, your middle initial, and your date of birth. Is that good enough to resolve all cases? No, it's not. What could we easily ask, as you get asked all the time in other cases of identity resolution, you know, applying for a loan or something, you get asked for your current street address, your current phone number, the last four digits of your

Social Security number. The key point is, the data need not be complete, it need not be unique, and it need not be all accurate. There are good technologies for approximate matching on things like this, and there's of course a whole field of computer science for varying levels of maintaining privacy or zero knowledge or whatever going off into the theoretical stratosphere.

But this is also very practical stuff. There are people who sell identity resolution products. There's a division of IBM, a piece of IBM that was founded by Jeff Jonas, I have that name in my next bullet, so patient identity is maintained by the DEAS but it's maintained dynamically. There's not some static database that has records of everybody all the time. In particular, Jeff Jonas describes ways of doing this to minimize—I say here—type one, type two errors. I mean both false positives in emerging identities and false negatives in failing to bring together a single patient's record to make those very rare and essentially to keep updating that, because as new information flows through the system that information helps the system be able to identify that patient in the future.

An important point here is that the identity services handle identity data that is personal data and it will be handled with appropriate safeguards, as I'll talk about in a second, but the identity services should never see clinical data. They shouldn't even see it in transit. There should be a strict separation between the identity services and the actual clinical data. So what do the identity services do? They return to the application that wants to find a patient's data, pointers to the data wherever it may be out at the level of the individual providers that hold the data, or at larger federated holders of the data as may develop or as policy may dictate. Once again, we're trying here to be agnostic about what the policy is and provide for the various possibilities. Okay, quick comments on slide eight and I'll move to slide nine.

Tim Elwell – Misys Open Source Solutions – Vice President
How does this differ from the current probabilistic matching algorithm capabilities of many of the MPIs today?

Bill Press – PCAST – Vice Chair
I don't know the answer to that at a technical level, so I think that's a good question.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
When you refer to a division of IBM, I think you're talking about Initiate.

M
No, I just looked him up. Jeff Jonas is not part of Initiate, though. He's a distinguished engineer for IBM. I thought the same thing, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
We took testimony from IBM, who's the leading vendor in healthcare in this and who has a lot of information about false negatives and false positives. From other researchers and vendors a few weeks ago, and they talked about error rates that are tunable by changing the balance between false positives and false negatives, but still were in the 0.1% range at best if you tuned for that parameter against the other. I'm just wondering if the PCAST committee is assuming that the error rates can be gotten much smaller and I'm also confused because we've been talking about a system that seems to be retrieval oriented and here you talk about capturing information out of the data flow. If the system is retrieval oriented I don't know what data flow there is to capture the information from.

Bill Press – PCAST – Vice Chair
Okay, good questions. I think PCAST is assuming that if there is a universal exchange language the error rates can be made much less. The reason is actually on a bullet that I skipped here—somewhere buried down in the middle—where the protocol has to allow query back in unusual cases. So let's say that those unusual cases are the 0.1% or whatever it is, because not in health IT but in other areas where I've seen systems like this it's very often that the system knows whether this particular case is the case where it's likely to be making either a type one or a type two error. It can recognize some degree of ambiguity. So I just put in the little fanciful example, the query back has asked the patient if he was ever treated in Cincinnati.

Now, I see this all the time just as a consumer on the financial industry. I log on to financial Websites that, to identify me, give me a list of street names and ask me to identify one out of the five that I've previously lived on. My guess, maybe we have an expert on this call on those systems, but my guess of the way they engineer that is some of those street names are spurious so that less information is ever revealed to the user, but that two out of the five are probably resolving some ambiguity. I think the path forward to achieve much lower error rates than a tenth of a percent would be that it be a closed loop system, not an open loop system, where you have to just tune it once and accept whatever rates you get.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
But doesn't a closed loop system, assuming that the patient is available for the interaction, significantly limit the ability to use this for research and public health and even many, many times where a physician is working on the record of a patient without the patient being right there?

Carl Gunter – University of Illinois – Professor
For research, you might be less likely to need the exact name of the patient.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
But the question is if you're assembling data about patients who have had this treatment and that treatment and this problem and you're not sure that you're really matching up the same patient—

Bill Press – PCAST – Vice Chair
Okay, I think those are good questions and I think that can be a longer discussion. I think the simple answer— Well, there is no simple answer. I think in research there are always data errors and one kind of data error is the possibility that you're actually merging the records of two patients, both anonymized. Or another possibility is that you're not seeing a complete record of one patient. But by the time you're at levels below a tenth of a percent I think those are manageable on the research side. On the clinical side, I guess the way to say this is I've given as examples identity data here that probably gets you to the tenth of a percent level, but there's all kinds of other identity data that would not be routinely circulated or routinely used, but could be used on these rare queries. Paul, may I push on?

Paul Egerman – Software Entrepreneur
Absolutely. I think that's a good idea. I think this is an issue, I hear some of the concerns, and we wrote down something about privacy, but we should write down this is an issue. I think a few eyebrows are raised on this one, but let's move on.

John Halamka – Harvard Medical School – Chief Information Officer
I have joined the call.

Paul Egerman – Software Entrepreneur
Great, glad to have you, John.

Bill Press – PCAST – Vice Chair
Hi, John. I'm on slide nine now about data security. I think this is the heart of how privacy restrictions, not to mention also the security itself, are enforced. PCAST feels strongly that all data should be encrypted all the time in transit and at rest, and that the decrypt, when it occurs, should be at the point of use. The decrypted data should be treated as volatile, namely, it's used for whatever the intended use is immediately at a single point in space and time and that decrypted data in general would not be locally stored by the application or a person who is using it beyond the immediate use. The point here is that bringing together, to do an encryption you have encrypted data and you have a key, the point here is we think the structure should enforce that bringing data together with key is always an auditable transaction. So one of the other functions of the DEAS is essentially to do this auditing function, to be able to say this datum on this patient was decrypted at such-and-such a place and time and for such-and-such a stated purpose.

Robert Kahn – Corporation for National Research Initiatives – President & CEO

Bill, I just wanted to clarify one part here. Part of it was just semantics, so when you say data encrypted all the time, you really mean all the time except when it's not encrypted, namely at the point of use?

Bill Press – PCAST – Vice Chair
Yes, of course. Obviously to use it you have to decrypt it, but our view of the point of use is not that it enters some provider's healthcare system. Our idea of the point of use is there is a specific program application running on a specific box that is going to display this data or in some other way process this data.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
That's where I want to get to. I clearly don't think you mean to control the kind of devices that somebody can use to access this data because ultimately any app that you have can be undone if somebody has access to the machine and is technical enough.

Bill Press – PCAST – Vice Chair
Of course, of course—

Robert Kahn – Corporation for National Research Initiatives – President & CEO
... has to be encrypted, are you talking about that as a guideline for the system or a government policy that somehow you try to enforce it? Because I can imagine lots of doctors and users trying to download data and then they do something, like try to store it somehow if they can.

Bill Press – PCAST – Vice Chair
No, but this is a design criterion for any apps that we're going to certify to come on to this encrypted network and it's that they not store the data. By the way, if the doc wants to store the data, there's no problem. They click the store key on their app and it, from a user's perspective, stores the data. But what actually happens is if it stores the data at all it stores the encrypted form of the data and the next time they want to display it, it generates another auditable transaction—

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Fine, I'm okay with that, but it sounded like this is policy and I think what you want to say is policy for the design of an app.

Bill Press – PCAST – Vice Chair
Yes, but it's also policy for regulation, because you actually want to make it illegal at some level to write an app that does not enforce the policy of data encrypted all the time.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I'm fine with that. I just wanted to get it clarified.

M
Just to comment on the depth, the width, and the breadth of the policy here, the effect of this policy is to tell healthcare delivery organizations that they will be making decisions that they will have to defend forensically without the ability to retain the data upon which they made the decision. That will achieve substantial resistance from healthcare delivery organizations.

M
I think in this case you will be keeping the encrypted version of the data and so you would simply rejoin the key with the—

M
So if somebody has invalidated that key, changed the privacy regulations, privacy requirements on it and is now suing me based on it, they have the upper hand.

Bill Press – PCAST – Vice Chair

Actually, I think that's a great point. I hadn't thought of that, but I think that's completely within the system. I think as an engineering way to do that you would want a mode by which a provider can keep data encrypted but there will be a protocol for request new encryption key for this data and that key will not be held by them. The key will be held by the infrastructure but it will be tagged as this key is for the purpose of this provider's responding to queries about why that decision was made, and that would be auditable.

M
There's an issue about will people trust that, but let's let that go by. Typically clinical decision support, the advantage of the computer is you can review a whole lot of data every time you make a decision that a person wouldn't possibly do. But if each of those datums requires a separate interaction to retrieve and unlock, even in the advances of networking and cloud computing and everything else, it's still an untenable level of overhead—

Bill Press – PCAST – Vice Chair
No, I don't think so. I don't think so. I think the level of overhead implied by the encryption is not –

M
No, it's the access, right? It's accessing the key through the network delays associated with accessing the key and/or accessing the data, depending on where the data is stored.

Bill Press – PCAST – Vice Chair
I don't think so, because when you say the physician, this is all user transparent to the physician, because the user never even knows that there's encryption/decryption occurring here. Now, you'll say, okay, that—

M
No, I'm assuming that. I'm just saying—

Paul Egerman – Software Entrepreneur
I need to break into this a little bit. Again, it's a very interesting discussion, but I'm looking at the clock and I want to make sure we get through everything. I'd like to address this issue at a slightly different level, which is to simply say how should we be interpreting the PCAST Report on this issue and a lot of other issues? In other words, if what we do is to say, well, on this issue of storing we think the real issue is data security and encryption, as long as we guarantee that in terms of storing, lots of concepts about local caches or a lot of other things and we're going to give a lot of flexibility on it, we're just going to ensure our security. So my question is, how literal are we supposed to take the PCAST Report? Is the general direction—?

Bill Press – PCAST – Vice Chair
Yes, absolutely.

Paul Egerman – Software Entrepreneur
… if so because the storage thing is something else, it's very controversial, it's we're not going to do that piece. We're just going to make sure we've got the data security piece right.

Bill Press – PCAST – Vice Chair
I think to answer the question is yes, the PCAST Report is directional in nature. Now, it gets more specific when we think that someone following this general direction could stumble into pitfalls that we spent some time talking about and that we wanted to prevent people from talking about. I think in this case the pitfall is the standard newspaper headlines that we all hate to read that says a laptop was stolen that had 5 million peoples' personal information on it. We believe that those kinds of incidents and their analogs in healthcare are always going to happen if there are large organizations that control in an unaudited way both the encrypted data and the encryption keys. So in a directional sense the PCAST Report says you should view the holding of encryption keys as a different function from the holding of clinical data and try to separate them.

Paul Egerman – Software Entrepreneur
This is about whether or not you store data from another system, is that something that's directional around security? Or we say, well, here are operational reasons why we want to do something different but we're just going to come up with a different solution for security?

Bill Press – PCAST – Vice Chair
I think that's up to you.

Paul Egerman – Software Entrepreneur
That's what I'm trying to understand. So that is very helpful.

Carl Gunter – University of Illinois – Professor
Can I interject here? We currently encrypt all the data in transit, and I took the report to be recommending we ought to try harder to encrypt the data at rest. If the goal is just some ..., let's try to be secure, the report is not really recommending anything much. But if there should be much more substantial effort to encrypt data at rest, that's a substantive recommendation.

Bill Press – PCAST – Vice Chair
Yes, that's correct. But also it says you could engineer a system that has all the data encrypted at rest and you gain no security benefit from it if the keys are held by the same organizations or on the same machine hardware that holds the encrypted data.

Paul Egerman – Software Entrepreneur
I'm sorry to start interrupting people, but I'm also looking at the clock and I want to make sure we get through everything. I apologize to you, Wes, because I knew where you were heading on this, but if you don't mind, Bill, let's go on to the next issue.

Bill Press – PCAST – Vice Chair
Okay. The next issue—I'm still on slide nine. I'm down on the first point in commentary—is another part of the whole data security and privacy issues is although we've taken for patients the position that there doesn't have to be a uniform patient identifier, for providers we're essentially taking the polar opposite position. We're saying that the technology exists to have strong, fine-grained identity—somebody's feeding back—authentication for providers and that this, when we say fine-grained we mean that identity should be established down to the level of the individual in the institution interacting with this computer running this program, and importantly also be role-based. Namely, an emergency room doc probably needs information faster and with less interference than, I don't know what the opposite example is, a primary care physician using a computer from home or something.

Paul Egerman – Software Entrepreneur
I just want to ... to tell that primary care physician ....

Bill Press – PCAST – Vice Chair
I'm sorry. I shouldn't insult anybody here. If there are members of the public listening who are primary care physicians, we need you. Okay, I'll skip the rest of this slide. It's sort of at a technical level but it's the next level of implementation of this idea that bringing together data and key should be an auditable transaction because that's something that computers can do and that traditional, say, paper record storage can't do, is keep an audit trail.

So I'm now on my last slide and because of the time to spare I'm not doing this in any level of detail, but I'll just tell you what the meta message here is. The meta message is, we've describe a whole lot of things that have to be done. We thought pretty hard about this question of, isn't the list of things that have to be done just too long because if I first do this and then do this and then do this we'll never get there in the context of the very real time scale for the meaningful use standards. Our belief is that the kinds of structures that we've described, the exchange language and the data access services authentication identity crypto auditing, that these can be teased apart, as one would do in engineering

management of any large software project, into things that can be accomplished quickly and in parallel. It's just a wag, but we actually went out to some people in industry and we said, this kind of a project, how big is it? Is it three people in a garage working for two months? No, it's not. What's the scale of it? We got some fairly consistent estimates in the range down here in the yellow box on slide ten of $20 million to $40 million. So that's 60-120, or something, person years of effort.

M
Could you define deliver? Do you mean to create specifications, or to roll it out to the industry?

Bill Press – PCAST – Vice Chair
I think we mean both at some level. The blue box at the bottom says if we—and the "we" on this are the people in the working group and on PCAST who have experience in this kind of thing—we would give priority to reference implementations on this and essentially let the perfect standard documents follow along.

M
So create a reference implementation as opposed to a standard, I think that's a discussable point that has some moxie to it. The question that I'm asking, has this got to do with the cost to the industry of putting this in place?

Bill Press – PCAST – Vice Chair
No.

M
Or the cost of developing what it is in order to consider putting it in place?

Bill Press – PCAST – Vice Chair
Number two. Now, we also have some cost estimates, and like all cost estimates trying to do things across all industries they're very, very rough. But we have in the report some cost estimates of the other question, of what is the cost going to be to industry to implement this? But here the $20 million to $40 million is supposed to be the cost of rolling out open source references and putting in place the Light DEAS side implementation to allow it to be rolled out to the industry. I might as well declare that I'm done and that we're in the discussion period, because I've more than used up all the time for ... the presentation.

Paul Egerman – Software Entrepreneur
First of all, Bill, you've got a lot of questions and in one sense we're way over time and in another sense these are important questions, which is why I just thought that you might as well go ahead and do it, because it's terrific you agreed to give us so much of your time. So I just want to tell you that I appreciate it.

I have one question that I want to ask and then I'll let other people ask questions. My question is, are there examples of any other industries where this kind of structure, the universal exchange language, the DEAS, are there any examples of any other industries where it's been implemented successfully?

Bill Press – PCAST – Vice Chair
I think the way to say it is the underlying technologies all exist, that I don't think anything that we're suggesting here is a technology that hasn't been used in large scale somewhere. I think putting it all together is probably unique to health. Let me give you examples. Exchange of information using XML-like languages, is a huge industry, huge success, that's sort of why XML has this magical aura that maybe it does or it doesn't deserve. What about the identity resolution, or more generally the record location? Well, there we view the underlying technologies as being the same technologies that go into Web search engines. This is different. There are different layers of encryption and protection on it. But the basic high bandwidth exchange of many, many small pieces of information is absolutely what makes the Web work and many things that ride on the Internet work; I should say that makes the Internet work. I

think if you wanted to point to any particular thing and challenge us to say where has this technology been demonstrated at scale? Our claim is that we can come back to you and give you examples of that.

M
I'd like to put that challenge up for the specific issue of recording business information obtained over the Internet in a manner that can only be unlocked by reference to an external key, outside of the intelligence industry, of course.

Bill Press – PCAST – Vice Chair
Well, I was about to give the example of—

M
Oh, good, good.

Bill Press – PCAST – Vice Chair
—of the intelligence industry.

M
I think there there's a level of trading off the benefits of getting access versus not getting access and how much do you expect to have to forensically defend your decisions that may be enough different for the intelligence industry that it's probably a hard comparison to make.

Bill Press – PCAST – Vice Chair
Yes.

Carl Gunter – University of Illinois – Professor
I was going to say that for this thing with the keys there are several major companies that have systems like that.

M
We're talking about the cost to the industry of adoption and the success of having adopted that philosophy. There are products out there to do this for sure.

Carl Gunter – University of Illinois – Professor
... major operational systems that use that technique with very large amounts of data.

M
Okay, so I'm asking where, the banking industry, the insurance industry, aerospace? I've just never heard of it.

Paul Egerman – Software Entrepreneur
... three or four million healthcare workers in the United States, is that a good estimate? Is the issue that can you get three or four—?

M
No, the question is in any industry have the private organizations that are the manufacturers or distributors or otherwise provide the value of the industry, adopted across the board a method of sharing data for business transactions where they will end up leaving the data in a way that they don't have access under their own control. They require a third party to give them access to it. I just don't know of any.

Bill Press – PCAST – Vice Chair
Okay. So here's a good example where, the PCAST Report is one report and PCAST moves on to other issues. I think as individuals—the members of this working group—are interested in staying involved in this, but you folks are a continuing group, or ONC has a continuing mission in these areas. You can come back and say PCAST is naïve in thinking that team management can be centralized to the extent

that they describe and for these, what I would call business model reasons. You can say here's what we propose for key management. And I think if what you propose for key management was each organization keeps the keys to its own data by its own policies and with no visibility to the federal regulatory apparatus, PCAST would say no, that's not what we meant at all. But if you were to say, here are a set of standards for distributed key management that we believe gives the appropriate level of security and privacy and—

Paul Egerman – Software Entrepreneur
If I'm hearing you right, Bill, you're saying we should review this report in general as directional. So there are pieces that we find troubling and if we give an alternative that heads in the same direction that's consistent with the report. Is that what I'm hearing?

Bill Press – PCAST – Vice Chair
Yes, I think that's generally true. Then I think we would reserve the right to ask for an opportunity to come back and say no, your solution is not along the directions of the PCAST Report, and here are the reasons and the detail why.

Paul Egerman – Software Entrepreneur
How do we coordinate that? What's the vehicle for having that dialogue that you're describing? It's a healthy dialogue because I've learned a lot in this discussion, and I hope other people have also, but it would be very easy for us to go forward for another two months if we don't have any communication with you and find out that there's some big gap. How do we have the dialogue you just suggested?

Bill Press – PCAST – Vice Chair
PCAST has a small number of members and is a small organization, so generally on this particular report it will come down to the co-chairs, Chris Cassel and Craig Mundie and myself as the PCAST Vice Chair who had responsibility for this report. We're ready as individuals to dialogue with you and it can be coordinated through the PCAST executive office. I don't know any other answer, because it's not that PCAST is backed up by a standing health IT division or something.

Paul Egerman – Software Entrepreneur
Other questions that members have?

Tim Elwell – Misys Open Source Solutions – Vice President
Just one clarification question and then a real question. On the $20 million to $40 million bill I think that foots or at least maps to page 60 on estimating cost, which is point number one, which talks about developing standards for the universal exchange language, and then its associated privacy and security protocols. Based on my estimations if you add two, three and four you're looking at around $1.6 billion to about $6.3 billion based on the number of HR vendors, as an example, in the industry. So putting that ..., I just want to make sure that we're not saying that the estimation is only $20 million to $40 million.

Bill Press – PCAST – Vice Chair
You're absolutely right. Now, of course, the large costs are borne in different ways, and page 60 is the right page so I guess I'd defer people to that page for a somewhat more nuanced discussion of where are the costs and who will bear them and over what time scales.

Tim Elwell – Misys Open Source Solutions – Vice President
Great, and the second question, follow up, was, in your examination of current industry standards and directions that the industry has taken in specifically healthcare, was it your determination that the clinical document architecture is a failure then, in that it does not meet the needs of the industry?

Bill Press – PCAST – Vice Chair
I don't think I am expert enough to answer that. I think our belief is that it alone is not a sufficient platform to proceed on, but I don't want to misspeak as a non-expert in the clinical document architecture specifically.

Richard Platt – Harvard Medical School – Professor & Chair
Can we come back to the identity resolution question, please. When you talked about a 0.1% error rate, is that about the order of magnitude that we can expect in real practice?

Bill Press – PCAST – Vice Chair
I used that number because I heard it on this call, in this conversation.

Richard Platt – Harvard Medical School – Professor & Chair
I think Wes gave that number, but I suspect he was talking about the extent to which you can modify the error rate. Because obviously that's the same hearing he was at and people were talking about error rates in the range of 10%. Is that right, Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think that the low end of the ranges, particularly for false positives, were lower, along with the caveat that in order to get one low you had to tune against the other. I thought that Bill's answer here about making that tuning a dynamic part of the query was a step in the right direction. But I still am puzzled about using the active mode of identity resolution as the basis for an approach that's designed to access information in various situations where the patient may not be present.

Carl Gunter – University of Illinois – Professor
Let me suggest a homework assignment. We should get some estimate of the number of times that resolution will fail for a medium size hospital that's using this technique. My concern is that error rates that are in the 10 to the -3 will be unacceptable in practice, because it will mean that there are many errors every day in every reasonable sized institution. I think that will probably be unacceptable.

Bill Press – PCAST – Vice Chair
That's probably true now, and it may be unacceptable, but I think that we're talking about a different situation in a hospital. They normally, for a patient who's in-house, they have done active remediation of the identity at the registration desk, at the admission desk. This is a different issue than interoperability across institutions.

Carl Gunter – University of Illinois – Professor
Let's not try to wrestle it to the ground now. But I think we should do the real quantitative estimate of how often we can expect, looking at an average day, that there will be meaningful misidentification.

Bill Press – PCAST – Vice Chair
We can pull that out of the testimony we had or contact those experts again. It's been studied a lot.

Paul Egerman – Software Entrepreneur
... that. So I wrote that down on the list. I think it's something that we can respond to and I think you can get that from the testimony. ... for time, if people have other questions open.

John Halamka – Harvard Medical School – Chief Information Officer
We can just ask Cris Ross, who operates the Surescripts Master Patient Index with 155 million lives, what their false positive and false negative rate is, because they're already using this technique for all ePrescribing in the country.

Paul Egerman – Software Entrepreneur
We will get an answer to that. My question is, do any of you have one or two last questions that you wanted to ask Bill Press?

William Stead – Vanderbilt – Chief Strategy and Information Officer
I would like to know if you have an example of a metric that you would suggest for recommendation, one, so the chief technology officer that's working with ONC would measure progress toward the proposed infrastructure, just one example of what a metric might be.

Bill Press – PCAST – Vice Chair
Let me see what page—

William Stead – Vanderbilt – Chief Strategy and Information Officer
It's off of page 77.

Bill Press – PCAST – Vice Chair
I don't want to define an answer by just making something up off the cuff. But for example, I think in our discussion of my slide ten where if you imagine some top level parsing of these things down into reference implementations that have to be provided, there's a metric as to how many of them have been achieved, what level of testing each one has achieved, what level of scaling up has been demonstrated. I think in the sense of accomplishing the standard writing and standard setting, or I should say records implementation writing, that's the kind of thing we have in mind. The purpose of that recommendation is to help be sure that we're all on a path that is actually moving and not just turning, right.

M
An Internet date, or something like that, was how many institutions were hooked up to some prototype Internet service.

Bill Press – PCAST – Vice Chair
Yes, and that would be a metric of adoption rather than a metric of progress towards standard, and I think we have in mind that, I guess this is a recommendation to the CTO of the United States, who's Aneesh Chopra. I think both kinds of metrics would be useful.

Paul Egerman – Software Entrepreneur
Bill Stead, do you have any other questions or is that adequate?

William Stead – Vanderbilt – Chief Strategy and Information Officer
All the rest of mine have been answered.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I have a question, Paul.

Paul Egerman – Software Entrepreneur
Go ahead, Dixie. This will be the last question, though.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, this is the one I wanted to ask earlier. I was wondering whether the PCAST group discussed how data elements could be tagged with privacy tags without outside context. For example, a particular lab value in and of itself may not be sensitive, but with several other lab values perhaps and other symptoms may indicate a diagnosis.

Bill Press – PCAST – Vice Chair
Yes, I think that's a good question and I think that's what I was trying to get at when I said how sophisticated a privacy vocabulary do you want and that the perfect might be the enemy of the good here. So I think just in terms of our internal discussions, an initial cut at this might just be the kinds of levels of privacy that current regulations require. It depends on different state laws and so on and so forth, requirements for consent, consent for use and research, if that's required by existing policy. Then there are obvious ones that everybody knows should allow for different levels of privacy, for example, mental health information or HIV information, and then the sort of more subtle points that you're raising of are there certain kinds of data where you want to look at how they're being used in combination. That might be a later evolution of this privacy description language than we need initially to get started.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's really not what I'm asking. I'm asking about your response and you used the word "information" which is at a much higher level of granularity than "data element." My understanding of your slides and

reading the PCAST Report is what you're recommending is that a data element level be the level at which the privacy will be attached. Is that correct?

Bill Press – PCAST – Vice Chair
Yes. But, for example, suppose that the situation now is that you have a patient clinical record that has many pieces of data on it, and suppose that policy now attaches some level of privacy protection to that whole record. Then that same level of privacy would be attached by default to every datum within that record.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I had to drop off for a few minutes, as I indicated before. Did you guys get around to the question I asked earlier? I didn't hear it. I also have a few comments. If I could make them I'd be happy to.

Paul Egerman – Software Entrepreneur
I'll tell you what, we have to do time also for public comment so I'll give you one minute, if you don't mind.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Oh, for my part? I was talking about your part. Did you talk about my question at all?

Paul Egerman – Software Entrepreneur
What was your question?

Robert Kahn – Corporation for National Research Initiatives – President & CEO
It had to do with understanding what you meant when you talked about this was widespread agreement PCAST but you weren't necessarily happy about it.

Paul Egerman – Software Entrepreneur
This was widespread agreement within PCAST of poor Internet adoption ....

Robert Kahn – Corporation for National Research Initiatives – President & CEO
And reliance on established technology versus new technology? I'll tell you what, let's put that question off and answer that separately.

Paul Egerman – Software Entrepreneur
Yes, let's defer that. The real focus of what we wanted to do here was to understand the report and that's an interesting aspect of the report but it's not necessarily something that impacts our work going forward.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Then I'll do just one minute's worth of brief comments here. I'm very concerned that the report is so tied to Web and Web dependence that it may not be able to deal with new technology in the future. There's a lot of tension between what I consider up front binding to the various structures and the ability to do deferred resolution. I think there's a real issue about long-livedness that I don't see really discussed. If you want to build these records and have them available 100 years from now, there are some specific things that ought to be mandated to help that out. There's a split in talking about things that I would view as applications dependent and infrastructure dependent, for example. All the work on TCP/IP and related things that are just used to move data at a lower level of the infrastructure are really different from the applications. I think we're going to see more of that as part of what's needed for the medical project becomes infrastructural and part of it becomes application dependent, and both of those will evolve in various different ways.

I think there's a whole set of questions about whether you can define the languages and the structures at a sufficiently high level meta description so that the details of what we've been talking about can be actually ... binding. I think finally there's the whole question of whether what the investment is, is suitable for taking advantage of the technology as it comes forward in time, and I'm just concerned that we may lock ourselves into things that don't let us take advantage of the newer stuff.

Paul Egerman – Software Entrepreneur
That was a whole lot of material. I appreciate that. I also wanted to say to Bill Press how much I deeply appreciate the amount of time he took. ... give you something of a grilling today and that this is a lot of material that approaches an area where many of us have done a lot of work for many years. You approach it from a very different standpoint, so there's a certain aspect of our questions that it will perhaps just take us a little while to understand the report. But I really very much appreciate your time. I do want to do public comments, but first ... do you have any last words for us? I feel like I'm on television ....

Bill Press – PCAST – Vice Chair
I appreciate the opportunity. I certainly recognize your last point, that PCAST, almost by definition, are amateurs, although of course we don't write a report without having the backing of a working group assembled from outside PCAST that maybe some of you were on for expert input on this. But I think a future dialogue on this is certainly very useful and I want to again emphasize that the PCAST Report is a single point in time trying to be a useful direction setting and it's up to continuing institutions like yours to figure out how the evolution actually does go.

Paul Egerman – Software Entrepreneur
That's terrific. That's a good way to summarize our challenge, is to look at PCAST and understand what are the exciting directions it has given us and find a way to mix that into the work that we are doing so that we can take advantage of those great concepts. The next meeting of this group will be on January 27th at 11:00 Eastern time, which I know is 8:00 for those of you on the West Coast. What we will be doing in the next meeting is one of the topics will be to start going through the public comments that we received in the public comment period. We will also be continuing with this entire discussion to make sure that we all are comfortable with where the PCAST report is.

Noticing that we're short on time, though, Bill Stead, do you have any other comments?

William Stead – Vanderbilt – Chief Strategy and Information Officer
No.

Paul Egerman – Software Entrepreneur
Okay. So, Judy Sparrow, can we open the lines and see if there are any public comments?

Judy Sparrow – Office of the National Coordinator – Executive Director
Operator, can you please check with the public and see if anybody wishes to make a comment to the workgroup?

Operator
We have a comment from John Matheson.

John Matheson
I have three very closely related questions and they're all related to the assumptions built into the PCAST Reports. The first one is, there's a very clear distinction being drawn between syntax and semantics as if they're unique and isolated notions. So the first question is, are you aware that the syntax version 3 of HL7 and associated with the clinical document architecture actually is mapped to a reference information model so that there are actually semantics that are embedded in the syntax? That's the first question, so they can't be artificially separated.

Secondly, you indicated that the CDA, in response to Wes' question, the CDA you couldn't ... whether it was flawed or not but you could state that it was insufficient by itself. Could you articulate what specifically is insufficient about the clinical document architecture?

Then the third question is about the underlying assumption of the problems trying to be solved. It appears that the assumption is that the reason uptake of standards is low is because the standards themselves are flawed and there's an alternative root cause that would look something like if there isn't

stability in the federal guidance around the standards why would vendors invest the money to adopt a volatile and inconsistent approach? If that is relevant as a root cause, then proposing an entirely new standard only compounds the underlying problem that we're attempting to solve, so I'll stop.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. Matheson. We really don't answer questions on this portion of the call, but we will certainly take that under advisement. Are there any other public comments?

Operator
Yes, our next public comment comes from David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
The previous question covered one of my points, which is I would like to know more about what the PCAST committee were the deficiencies in CDA. Second is, I agree with Dixie's concerns about the static binding of the privacy elements. It seems to me that if the privacy concern is a function of what kind of data it is, then that could be done dynamically. It also seems like if it's statically bound you would limit the patient's ability to change their mind as their context changes. Also, of course one man's public data is another man's private data, so the notion that you could statically type it seems to be a little bit problematic.

Third, I'd like to agree with Wes that I think it would be a considerable issue if the decryption key was not under the control of a provider who had incorporated a response to data in his management of the patient. And would propose that once the data crosses inside the firewall that has met the HIPAA privacy and security requirements, that I wouldn't see the need necessarily to keep it decrypted. On the other hand, I think the notion that decryption is an auditable event is a terrific idea. I've got a couple of other thoughts, but I'll stop there.

Operator
Our next comment comes from Carol Bickford.

Carol Bickford – ANA – Senior Policy Fellow
I was struck by the comments within the document that the populations of concern were going to be the physicians and the physicians and the physicians and facilities like hospitals. It seemed to me that there's a much greater cohort of folks that need to be attended to and that the solutions that were to cover the activities of the providers in the form of physicians and hospitals may not work for the other entities, for example, long term care, home health, ambulatory care, and other clinicians.

Operator
Our last comment comes from Pam Tweed.

M
... with Private Access. The comment basically is to the effect of somehow both the named but also disregard for accounting for disclosures and the disclosure clause associated with this information, how PCAST handles that on a sustainable basis. So it's an area that obviously I'm not addressing the question, but as much as it's an area I'd like to see some expansion or attenuation of thought on as to why that was obviated out of PCAST.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you for all of those thoughtful comments. I'll turn it back over to Paul Egerman and Dr. Stead.

Paul Egerman – Software Entrepreneur
Thank you very much. I would like to, again, first, thank the public comments. Those were excellent, excellent comments. For members of the public and also members of the workgroup, there is a few days left in the public comment period, basically ONC put a notice to the federal register. I think it ends either Monday or Tuesday.

Judy Sparrow – Office of the National Coordinator – Executive Director
I think it's Tuesday.

Paul Egerman – Software Entrepreneur
Tuesday, and so, for example, the comment we just heard about accounting for disclosures and Carol's comment about extended care facilities, I want to encourage you to consider writing those into Regulation.gov. We will be going through all that material, dare I say we will be discussing that material at our next call.

Jodi Daniel – ONC – Director Office of Policy & Research
Paul, can I just clarify one thing on the timing?

Paul Egerman – Software Entrepreneur
Yes.

Jodi Daniel – ONC – Director Office of Policy & Research
We just extended the deadline until Wednesday of next week because some people had asked for an extension, particularly since our deadline was on a federal holiday. So just by way of letting folks know, Regs.gov will be open for two extra days.

Paul Egerman – Software Entrepreneur
Yes, thank you. The reason I'm pointing it out is I know it's late on a Friday, but there may be people listening and this is a topic that is really very important and there's a lot of opinion on it, and we want to make sure that we hear it all. So I want to thank the members of the public who called in for public comment and I want to thank of course the workgroup members. A special thanks, again, to Bill Press. I really appreciate the fact that you gave us so much of your time and were so generous of your time. It was extremely helpful. Of course, I want to thank the ONC staff, Jodi Daniel and Judy Sparrow and wish everybody a happy long weekend.

Bill Press – PCAST – Vice Chair
Thanks, Paul.

Paul Egerman – Software Entrepreneur
Take care.